Title: Age of Sale - Nicotine Inhaling Products IA No: 3132 Lead department or agency: The Department of Health Other departments or agencies: Type of measure: Secondary Legislation Contact for enquiries: Policy Lead - Andrew Black, Analytical Lead - Rob Unsworth

Summary: Intervention and Options

Cost of Preferred (or more likely) Option							
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Measure qualifies Two-Out?				
-£0.64m	-£0.64m	£180k	Yes	In			

What is the problem under consideration? Why is government intervention necessary?

Nicotine is a potent pharmacological agent, is highly addictive and can permanently affect the development of the adolescent brain. The Government has legitimate concerns about young people becoming addicted to any substance before they are able to make informed, adult decisions. As nicotine inhaling products, such as electronic cigarettes, are currently legally available to under 18's, there is a risk that they could act as a gateway into tobacco smoking if young non-smokers become addicted to nicotine. While the evidence-base regarding gateway effect remains limited, there is not sufficient evidence to rule out e-cigarettes acting as a gateway into smoking tobacco.

What are the policy objectives and the intended effects?

The policy objective of the regulations is to limit the sale of nicotine inhaling products, such as electronic cigarettes (and related products including refill cartridges and nicotine liquids) to adults only, with certain limited exceptions for medicinal products. The intended effect is to limit the availability of nicotine inhaling products to young people and therefore restrict the scope for young people to become addicted to nicotine and any potential gateway effect into smoking tobacco.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do Nothing

Option 2: (preferred option): The option of (a) introducing an age of sale of 18 years for nicotine inhaling products together with (b) an offence of proxy purchasing nicotine inhaling products by adults for children is preferred. This is the preferred option as it is considered to be the most effective, proportionate and practical option.

Option 3 (non regulatory): Introducing a voluntary agreement with retailers that they will not sell these products to under 18's.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: Oct/2019							
Does implementation go beyond minimum EU requirements? Yes							
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes/No	< 20 Yes/No	Small Medium Lar o Yes/No Yes/No Yes				
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)				Non-t	raded:		

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by	the responsible	SELECT	SIGNATORY:
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RPC Opinion: RPC Opinion Status

Summary: Analysis & Evidence

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base		Time Period	Net Benefit (Present Value (PV)) (£m)					
Year 2014	Year 2014	Years 10	Low: Optional	High: Optional	Best Estimate:			

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

This is the baseline against which other options are assessed

Other key non-monetised costs by 'main affected groups'

Loss of consumer surplus by purchasing e-cigarettes to satisfy addiction, rather than through rational choice.

Health effects of developing a nicotine addiction and potentially a tobacco addiction if e-cigarettes are used as a gateway into tobacco smoking.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

This is the baseline against which other options are assessed

Other key non-monetised benefits by 'main affected groups'

Ability of under 18's to purchase e-cigarettes for the purpose of smoking cessation.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

We assume that a percentage of under 18's will use e-cigarettes as a gateway into tobacco smoking and will develop an addiction to tobacco. We acknowledge that further research is needed to answer the 'gateway effect' question definitively.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as	
Costs: 0	Benefits: 0	Net: 0	No	Zero net cost	

Summary: Analysis & Evidence

Policy Option 2

Description: a) Introducing an age of sale of 18 years for nicotine inhaling products and b) Introducing an offence of proxy purchasing nicotine inhaling products by adults for children

FULL ECONOMIC ASSESSMENT

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)				
Year 2014	Year 2014	Years 10	Low: Optional	High: Optional	Best Estimate: Positive		

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate			0.064	0.64

Description and scale of key monetised costs by 'main affected groups'

Direct cost to e-cigarette retailers, manufacturers and distributers from reduced profits as a result of removing the under 18's market. Retailers: £1.37m PVC 10 years. Manufacturers: £0.28m PVC 10 years. Distributers: negligible

Assumed half of these profits flow to other firms as spending is redistributed in different sectors.

Other key non-monetised costs by 'main affected groups'

Possible cost to under 18's that currently use e-cigarettes as a smoking cessation device – although evidence is weak on this point.

Loss of consumer surplus to youngsters who would have gained pleasure from e-cigarettes in excess of their cost.

Health effects of preventing a gateway out of tobacco smoking for those under 18's that wish to use ecigarettes as a smoking cessation device.

BENEFITS (£m)	Total Tra (Constant Price)	ansition Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate			N/A	N/A

Description and scale of key monetised benefits by 'main affected groups'

None

Other key non-monetised benefits by 'main affected groups'

Avoiding the loss of consumer surplus from young people consuming e-cigarettes to satisfy addiction, preventing them from getting satisfaction from other goods. Such gains endure into adulthood for as long as the addiction would have lasted.

Health benefits to individuals prevented from developing an addiction to nicotine and, potentially, tobacco use.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

We assume that a percentage of under 18's will use e-cigarettes as a gateway into tobacco smoking. We acknowledge that further research is needed on this particular issue.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 242.5	Benefits: 0	Net: 242.5	Yes	In

Evidence Base (for summary sheets)

Rationale for intervention and intended effects

1. Given the emergence of e-cigarettes in recent years, coupled with concerns about their use by children and young people, the Government took the opportunity offered by the Children and Families Act to introduce regulation making powers to set a minimum age of sale for these products. Section 92 of the Act 2014 therefore includes regulation-making powers for a prohibition of sale of nicotine products to persons under 18 years of age. Health ministers will undertake a public consultation regarding the use of these regulation-making powers to inform decision-making. The public consultation will also include the draft regulations and a consultation-stage IA.

Policy objective

- 2. The policy objective of the regulations is to limit the sale of nicotine inhaling products, such as electronic cigarettes (and related products including refill cartridges and nicotine liquids) to adults only, with certain limited exceptions. The intended effect is to limit the availability of nicotine for young people and prevent young people becoming addicted to nicotine before they are able to make informed, adult decisions. The regulations would not apply to tobacco products which are already covered by age of sale laws.
- 3. An electronic cigarette licensed as a medicine by the Medicines and Healthcare Products Regulatory Agency (MHRA), for example as a smoking cessation device, would be available to be sold to children under the age of 18 years if (a) it was sold in accordance with a valid prescription or (b) the product's medicine marketing authorisation provides that it is indicated for use by under 18s.

Regulatory proposal (Preferred Option)

- 4. The Department of Health proposes to introduce an age of sale requirement that will be limited to "nicotine inhaling devices", which would include nicotine inhaling products such as electronic cigarettes (the term "e-cigarette" used throughout this document is intended to encompass all nicotine inhaling products). The age of sale requirement will apply to disposable and rechargeable devices and their refills (such as pre-filled refill cartridges and nicotine liquids).
- 5. The regulation-making powers in the Children and Families Act 2014 require that any age of sale requirement for nicotine inhaling products be introduced for persons under the age of 18 years.
- 6. The government proposes that any nicotine inhaling products that are licensed as medicines will be regulated already relevant medicines legislation and will only be available to children in certain limited circumstances.
- 7. The regulations would make it an offence for a retailer to sell nicotine inhaling devices (and related products) as defined by the regulations to anyone under the age of 18 years, consistent with existing legislation relating to the sale of tobacco products.
- 8. A retailer convicted of selling a nicotine inhaling device to a person under the age of 18 years would be liable on summary conviction to a fine not exceeding level 4 on the standard scale (currently up to £2,500 but due to increase to £10,000 later in 2014). This level of fine is consistent with the corresponding tobacco age of sale offence. In addition, Restricted Premises Orders and Restricted Sales Orders that are currently issued by the court to retailers found to be persistently selling tobacco to people under the age of 18 years will be extended to include the sale of nicotine inhaling devices. Such an Order, if granted by the court, prohibits a named individual, or a named retail outlet, from selling nicotine inhaling products or tobacco to anyone for a period of up to one year.
- 9. The government also proposes to extend new "proxy purchasing" laws at Section 92 of the Children and Families Act to also cover nicotine inhaling devices, meaning that adults will not be permitted to buy products covered by these regulations, or tobacco, on behalf of children.

10. Subject to consent being provided by Welsh Ministers, the regulations would apply to England and Wales.

What are e-cigarettes?

11. Over the past 5-10 years, the market for electronic cigarettes (also known as e-cigarettes) has developed rapidly. A wide range of different types and brands of e-cigarettes are on the market. According to a report on e-cigarettes commissioned by Public Health England (PHE), e-cigarettes were invented in China in 2003 and designed to provide inhaled doses of vaporized nicotine. Electronic cigarettes were first introduced to Europe in about 2005 and become increasingly popular since. The products have evolved and improved considerably.¹ Action on Smoking and Health (ASH) has provided the following description of electronic cigarettes:

Electronic cigarettes, also known as vapourisers or electronic nicotine delivery systems (ENDS), are often, although not always, designed to look and feel like cigarettes. They have been marketed as less harmful alternatives to cigarettes and for use in places where smoking is not permitted since they do not produce smoke.

There are three main types of electronic cigarettes or vapourisers:

- Disposable products (non-rechargeable)
- An electronic cigarette kit that is rechargeable with replaceable pre-filled cartridges
- An electronic cigarette that is rechargeable and has a tank or reservoir which has to be filled with liquid nicotine

The first two types of electronic cigarette are often known as "cigalike" products as they resemble cigarettes and often have a light at the end that glows when the user draws on the device to resemble a lit cigarette. The liquid in the devices usually contains nicotine suspended in propylene glycol and glycerine. The level of nicotine in the cartridges may vary and most also contain flavourings. When a user sucks on the device, a sensor detects air flow and heats the liquid in the cartridge so that it evaporates. The vapour delivers the nicotine to the user. There is no side-stream smoke but some nicotine vapour is released into the air as the smoker exhales.²

- 12. Electronic cigarettes are often designed to look and feel like conventional lit cigarettes. Broadly, they can mimic the physical and social aspects of tobacco smoking. They have been marketed as cheaper and healthier alternatives to cigarettes and for use in places where smoking is not permitted since they are not lit and therefore do not produce smoke.
- 13. Most e-cigarettes on the market are flavoured. A huge variety of flavours for e-cigarettes are available, some of which may be appealing to children (such as cherry cola, white chocolate, bubble gum, vanilla ice cream, energy drink and gummy bear flavours).
- 14. E-cigarettes must not be sold as a smoking cessation aid unless they are regulated as a medicine by the MHRA. A number of e-cigarette companies have said publicly that they have submitted an application for a medicines licence for their product. At the time of writing, a license has been granted to only two products that would meet the definition of nicotine inhaling products: Voke and the Nicorette Inhalator. An e-cigarette that is regulated as a medicine, such as a nicotine replacement therapy, could still be made available to children under the age of 18 but by way of prescription only. Licensed medicines are subject to separate regulatory rules that cover aspects including advertising, product presentation, to whom medicines can be supplied and requirements relating to the sale and supply of medicines.

Use and awareness of e-cigarettes among children

Britton, J. and Bogdanovica, I. (2014). Electronic cigarettes: A report commissioned by Public Health England. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf

Action on Smoking and Health (2014). *ASH briefing: E-cigarettes*. Available at: http://www.ash.org.uk/files/documents/ASH_715.pdf

- 15. E-cigarettes are becoming increasingly popular and are now widely promoted. ASH estimates that there are currently around 2.1 million adults in Great Britain using electronic cigarettes, up from an estimated 700,000 users in 2012.³ While use of these products by people under the age of 18 is presently limited, international evidence suggests that it is plausible that usage of e-cigarettes by young people will increase.
- 16. Another report was commissioned by PHE on e-cigarette uptake and marketing, which provided information on the current situation regarding the use of e-cigarettes by children:

"Only one published nationally representative survey of e-cigarette use in children in the UK currently exists. This was conducted in March 2013 and did not include children in Northern Ireland but involved a sample of 2,178 11 to 18-year olds from Great Britain weighted to be representative of the population. It found that two-thirds (66%) had heard of e-cigarettes. Taking this group of children as the base (804 11 to 15-year-olds, 624 16 to 18-year olds), ever use, current use and dual use (with conventional tobacco cigarettes) was measured.

In terms of prevalence, 7% of 11 to 18-year olds reported they had tried e-cigarettes at least once and 2% reported using them sometimes (more than once a month) or often (more than once a week). Within the sample of those who had ever used e-cigarettes, 28% had used e-cigarettes within the last month. When prevalence was examined by age, 95% of 11 to 15-year olds and 90% 16 to 18-year olds stated they had never used e-cigarettes. Use was higher among the older teenagers: 11% of 16 to 18-year olds had tried e-cigarettes at least once; 8% reported using them sometimes (more than once a month); and 1% using them often (more than once a week). Among the younger age group, just 4% of 11 to 15-year olds had tried them at least once and 1% reported using them sometimes; none reported more frequent use...Among those 11 to 18-year olds reporting they had never smoked. 99% reported never using e-cigarettes and 1% reported they had tried them once or twice. Less than 1% of never smokers reported using e-cigarettes 'often' (<1% illustrates that the number was negligible but included at least one person). There were no 'sometimes' users. Among children who had tried smoking at least once, 8% had used an e-cigarette but none reported using them more often. The sample of current weekly 11 to 18year old smokers (smoking between one and six cigarettes per week) in the survey was very small (22 weekly smokers); 59% had never used e-cigarettes, 37% reported having tried them once or twice, 7% reported use more than once a month and 5% reported(1 person) use more than once a week".4

17. Emerging evidence suggests that awareness of e-cigarettes by British children is high, with over twothirds of children in Wales reporting that they have heard of e-cigarettes.⁵ In a study conducted among children in Cheshire and Merseyside, there were no children that had not heard of ecigarettes or did not know what they are. This study also found:

There was an overwhelming sense across all groups that the majority of young people who do use e-cigarettes do so not for the benefits proposed by those who produce and market these products (e.g. for health benefits, to save money, to allow users to intake nicotine in locations where tobacco smoking is prohibited), but simply "for the sake of it", to fit in with or impress their peers, or to portray a certain desired image of themselves. Although participants did not indicate that their friends put any direct pressure on them to try the devices, it was certainly the case that they felt that a young person would be more likely to want to try an e-cigarette if they had friends

Action on Smoking and Health (2014). ASH briefing: Use of electronic cigarettes in Great Britain. Available at: http://www.ash.org.uk/files/documents/ASH_891.pdf

Bauld, L., Angus, K. and de Andrade, M. (2014). *E-cigarette uptake and marketing: A report commissioned by Public Health England*. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311491/Ecigarette_uptake_and_marketing.pdf

Welsh Government (2014) Exposure to secondhand smoking in cars and e-cigarettes use among 10-11 year old children in Wales: CHETS Wales 2 key findings report.

that were using them. Friendship groups were considered very likely to share e-cigarettes and have collective experiences of their use.⁶

18. According to the PHE-commissioned report on e-cigarettes, there is evidence that in the US, use of electronic cigarettes has become more popular among young people with 'ever use' doubling between 2011 and 2012 from 3.3% to 6.8%, and current use increasing from 1.1% to 2.1%. Most of this increase has occurred as a result of use by people who already use some form of tobacco product.¹ However, another study of 11-17 year old males in the US found that while fewer than 1% of respondents indicated that they had previously tried e-cigarettes, 18% suggested that they would be willing to if offered one by a close friend.¹ Research also suggests that e-cigarettes have achieved 'substantial penetration' into the young market in South Korea, where rather than using e-cigarettes as an alternative to conventional tobacco cigarettes, most Korean adolescent e-cigarettes users are dual users with tobacco cigarettes.⁸ Based on this international evidence, it is plausible that e-cigarette use by children in Britain could continue to grow.

E-cigarette promotion and young people

- 19. The promotion of e-cigarettes is likely to be a key reason why awareness of these products is high among children. E-cigarettes are now available for sale, and are often prominently displayed, in a variety of different shops. E-cigarette companies compete on price and invest significantly in marketing and promotion, including through social media such as Twitter. E-cigarettes are also widely advertised, which has become a cause of concern for some. For example, the Faculty of Public Health says it is 'deeply concerned by the aggressive marketing and promotion of electronic cigarettes to young people'. 10
- 20. We have no reason to believe that e-cigarette makers are specifically advertising to children. The PHE-commissioned report on e-cigarette uptake and marketing states:

One of the reasons that e-cigarettes have become increasingly popular is the marketing of these products, which is currently difficult to regulate and has prompted calls for a consultation by the Advertising Standards Authority (ASA) in the UK. This marketing may appeal to children as well as adults.

21. While recognising that responsible e-cigarette manufacturers will not seek to specifically market e-cigarettes to children, there is a risk that some may be designing advertising and promotion for the young adult market. A Cancer Research UK report examined the marketing of e-cigarettes (including interviewing marketing experts) and found that 'independent e-cigarette companies appear to be actively targeting younger non-smokers or social smokers and promoting the e-cigarette as lifestyle products'.¹¹ Nevertheless, while e-cigarette companies may design their promotional activity to reach out to young adults, it is possible that this promotion may also resonate with young people. In April 2014, Sir Cyril Chantler published his independent review into standardised packaging of tobacco products, and described how promotional activity with respect to tobacco which is designed to reach out to young adults may also engage teenagers:

Hardcastle, K. and Bennett, A. (2014). "Most people I know have got one": Young people's perceptions and experiences of electronic cigarettes. Centre for Public Health at Liverpool John Moores University, Liverpool.

Pepper, J. et al. (2013). "Adolescent males' awareness of and willingness to try electronic cigarettes" in *Journal of Adolescent Health* 2013; 52(2), pp.144-50.

Lee, S. et al. (2014). "Electronic cigarette use among Korean adolescents: A cross-sectional study of market penetration, dual use and relationship to quit attempts and former smoking" in *Journal of Adolescent Health* 2014; 54(6), pp.684-90.

Juang, J. et al. (2014). "A cross-sectional examination of marketing of electronic cigarettes on Twitter" in *Tobacco Control* 2014; 23, pp.iii26-iii30.

Faculty of Public Health of the Colleges of Physicians of the United Kingdom (2014). UK Faculty of Public Health Policy Statement on Electronic Cigarettes. FPH, London. Available at: http://bit.ly/1j5HDAX

de Andrade et al. (2013). The Marketing of Electronic Cigarettes in the UK. Cancer Research UK, London. Available at: http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/cr_115991.pdf

I have seen considerable evidence of tobacco companies carrying out market research on all aspects of packaging (e.g. colour, size, shape and opening) to make it appeal to various target groups of young adults. In my opinion a "spill over effect" (as described by tobacco control experts) is extremely plausible, whereby packages that are meticulously designed to appeal to, say, an 18 year old, are highly likely to appeal to a 16 year old. Because 16 year olds look up to 18 year olds and want to emulate them, in my view it is not possible to design packages in such a way as to appeal solely to one group without also appealing to the other. Research looking at the link between branded and innovative packaging and childhood and young adulthood smoking susceptibility bears this out, describing an "inevitable knock on effect" of targeting product design at young adults. 12

- 22. The Cancer Research UK report concluded that particular marketing techniques can increase the prospects of e-cigarette advertising and promotion also appealing to youth, including through:
 - Independent e-cigarette companies present their products using a) cosmetic appeals (their attractiveness, coolness, colours and innovative packaging) and b) flavour variations across e-cigarette and e-shisha brands.
 - Social media platforms display attractive price incentives and promotional discounts.
 - Celebrities, their endorsements, and celebrity-inspired styling are common promotional tools in PR and advertising.
 - Online promotions use contests, sales apps and group discount vouchers for e-cigarettes.
 - Sponsorship for a range of sports is a prominent promotional strategy used by a number of independent e-cigarette companies.
 - E-cigarettes are described as being for sale at exclusive events, popular venues, on company and group voucher websites, via social media platforms, specialist shops, concessions and elounges.
 - For young non-smokers and social smokers, e-cigarettes are positioned as socially attractive and part of a rapidly growing trend.¹¹
- 23. Research undertaken in June-July 2013¹³ into the retail availability and in-store marketing of e-cigarettes in London found the following:

Our results show a high availability of e-cigarettes in small and large stores, with an overall availability of 57% (95% CI 48% to 67%) in our study sample. This is significantly higher than the 34% rate we found in an unpublished 2012 national study conducted in the USA, in the only other audit of e-cigarette availability. Given the recent increased investment in e-cigarettes by the tobacco industry, continued growth in e-cigarette availability is to be expected. Small stores had a noteworthy amount of e-cigarette marketing materials in the form of point-of-sale movable displays but not advertisements. Many of these point-of-sale movable displays engaged consumers directly by inviting them to try the product. We also noticed after beginning data collection that some small and large stores had e-cigarette brochures available at the point-of-sale, which can be included as a measure of the presence of marketing materials in future studies...

24. This study covered 128 stores across London (both inner and outer London boroughs). Audits were completed in 108 of the 128 stores identified. 57% of the 108 shops audited sold e-cigarettes. The distribution of e-cigarette sales in small and large stores was not significantly different.

Hsu, R et al. (2013). "An observational study of retail availability and in-store marketing of e-cigarettes in London: potential to undermine recent tobacco control gains?" in *BMJ Open*; 2013; 3.

¹² Chantler, C. (2014). Standardised Packaging of Tobacco: report of the independent review undertaken by Sir Cyril Chantler.

Available at: http://www.kcl.ac.uk/health/10035-TSO-2901853-Chantler-Review-ACCESSIBLE.PDF

- 25. According to the Government's *Tobacco Control Plan for England*, there is 'evidence that the display of tobacco products in shops can promote smoking by young people and undermine the resolve of adult smokers who are trying to quit. The Health Act 2009 ends the display of tobacco in shops'. However, the 2009 legislation only extends to tobacco products and does not apply to e-cigarettes (and related products) which can still be displayed openly and prominently in shops. Therefore, it is plausible that the increasing prominence of e-cigarettes in shops may increase the appeal for these products among children.
- 26. Research undertaken in Cheshire and Merseyside found that although some older adolescents appeared to associate e-cigarette use with smoking cessation, generally young people viewed e-cigarettes as a product in their own right, suggesting that many young people use them simply for the sake of it, for fun, or to try something new. According to this research, the main focus for young people was on the different flavours and designs of e-cigarettes and the opportunity for users to customise their devices and show individuality. The authors suggested that with their colourful designs and variety of flavours, e-cigarettes may provide a more accessible and appealing way for young people who may not like the taste or sensation of tobacco cigarettes to experiment with nicotine.⁶
- 27. A study among 11-12 year old girls in North Wales suggested that girls were very knowledgeable about the different flavours of e-cigarettes that are available and where they can be bought. For example, in two focus groups in Wrexham, girls talked about a pizza shop that sells e-cigarettes to children aged seven or older. The research also found that teachers at a local school in Wrexham confiscate e-cigarettes on a daily basis.¹⁵

The Potential for E-cigarettes to act as a gateway into tobacco smoking

- 28. E-cigarette use by children is strongly associated with tobacco smoking, and those children who smoke more are more likely to also use e-cigarettes. Survey-based evidence from the UK suggests regular e-cigarette use by children who have never smoked or have only tried smoking once is rare, the wider evidence-based regarding gateway effect remains limited. Nevertheless, there is not sufficient evidence to rule out e-cigarettes acting as a gateway into smoking tobacco for children, and further research is necessary to establish what role, if any, e-cigarettes have in encouraging the take up of tobacco use.
- 29. E-cigarette vapour is less irritating than tobacco smoke, making it easier for inexperienced smokers to inhale. Flavourings can also make the use of e-cigarettes more pleasurable for novice users compared to smoking conventional cigarettes, and a huge variety of flavours for e-cigarettes are available.
- 30. In her 2013 Annual Report, the Chief Medical Officer for England 'raises concern that there may be young people for whom e-cigarettes could be an entry point to use of conventional tobacco products, including cigarettes'. On whether e-cigarettes are a gateway into smoking, the UK Faculty of Public Health (FPH) says:

No longitudinal studies in the UK have examined whether electronic cigarettes serve as 'gateways' to future tobacco use. These data are urgently required. Until then, the precautionary principle suggests that it would be rash to dismiss the worrying trends in US children.

31. Based on current evidence, we cannot be sure that there is a "gateway" effect where e-cigarettes lead to tobacco smoking in children. Further research is needed to answer this question definitively.

HM Government (2011). Healthy Lives, Healthy People: A tobacco control plan for England. Department of Health, London.

Evans, K. (2014). Smoking in girls aged 11-12 years in North Wales. Social Change UK and Public Health Wales.

Davies, S. (2013). Annual Report of the Chief Medical Officer 2012 - Our Children Deserve Better: Prevention Pays. Department of Health, London.

32. E-cigarettes may facilitate the continued use of nicotine. A study of over 75,000 Korean adolescents found that e-cigarette use was strongly associated with current and heavier cigarette smoking, and that rather than being used as an alternative to conventional cigarettes, most e-cigarette users were dual users with cigarettes. This dual use may have negative implications for individual and public health because even low levels of cigarette smoking confers nearly the same risk of cardiovascular disease as heavy smoking and duration of smoking (as well as intensity) determines the risk of lung cancer. The researchers concluded that:

Despite the e-cigarette industry's claims that it markets only to adults, e-cigarettes have achieved substantial penetration into the youth market. As elsewhere with youth and adults, most Korean adolescent e-cigarette users are dual users with conventional cigarettes... Use of e-cigarettes is associated with heavier use of conventional cigarettes, which raises the likelihood that, like smokeless tobacco, actual use of e-cigarettes may increase harm by creating a new pathway for youth to become addicted to nicotine and by reducing the odds that an adolescent will stop smoking conventional cigarettes.¹⁷

- 33. A study of 40,000 young people in the US found that e-cigarette use among middle and high school students doubled between 2011 and 2012, from 3.1% to 6.5%. The researchers found that dual use of e-cigarettes and conventional cigarettes is high among adolescents. While the study was not able to identify whether most youths are initiating smoking with conventional cigarettes and then moving on to (usually dual use of) e-cigarettes or vice-versa, it suggested that e-cigarettes do not discourage the use of conventional cigarettes. The researchers concluded that 'e-cigarettes may contribute to nicotine addiction and are unlikely to discourage conventional cigarette smoking among youths'. 18
- 34. Many e-cigarettes are manufactured to look identical to cigarettes. E-cigarettes mirror smoking behaviours and may normalise smoking among children, particularly in places where smoking tobacco is no longer permitted by smokefree legislation introduced in 2007. E-cigarettes provide some of the additional behavioural cues that are known to be important in tobacco dependence, including the "hand to mouth" action. The potential role of behavioural cues and imagery associated with e-cigarettes in smoking initiation or smoking maintenance needs further research. Research in the US suggests that "passive" exposure to both e-cigarettes and to combustible cigarettes may evoke smoking urges in young adult daily smokers.¹⁹
- 35. While current technology e-cigarettes do not deliver nicotine as efficiently as cigarettes, the potential for these products to cause addiction to nicotine remains high. The German Cancer Research Centre says that:

Evidence in 2013:

Some young, non-smoking people might start using e-cigarettes, because they believe this to be less harmful than smoking cigarettes. Since most e-cigarettes contain nicotine, which is addictive, there is concern for young non-smokers who start using e-cigarettes developing nicotine dependence or, because of using e-cigarettes, becoming more familiar with smoking and eventually taking up cigarette smoking. Even though only a comparatively small proportion of adolescent non-smokers takes up using e-cigarettes, this still means that a new market of nicotine use and dependence opens and develops – with unpredictable consequences. ²⁰

36. The European Commission says that:

Study" in JAMA Pediatrics 2014; 168(7), pp.610-617.

Lee, S. et al. (2014). "Electronic cigarette use among Korean adolescents: a cross-sectional study of market penetration, dual use, and relationship to quit attempts and former smoking" in <u>Journal of Adolescent Health 2014</u>; 54(6), pp.684-690.

Dutra, L. and Glantz, S. (2014). "Electronic Cigarettes and Conventional Cigarette Use Among US AdolescentsA Cross-sectional

King, A. et al. (2014). "Passive exposure to electronic cigarette (e-cigarette) use increases desire for combustible and e-cigarettes in young adult smokers" in *Tobacco Control*. Published online first, 21 May 2014.

German Cancer Research Centre (2014). *Electronic Cigarettes: An overview – supplement March* 2014. DKFZ, Heidelberg.

E-cigarettes simulate smoking behaviour and can lead to further experimentation with other nicotine-containing products. Recent studies suggest that e-cigarettes are increasingly used by non-smokers and young people. For example a French study of 2013 revealed that the number of Parisian students experimenting with e-cigarettes has doubled in one year reaching 18%.²¹

Protecting children from addiction and the impact of nicotine on the developing adolescent brain

- 37. Nicotine is a potent pharmacological agent with established effects on the cardiovascular system and the central nervous system. Nicotine is highly addictive. The government has legitimate concerns about young people becoming addicted to any substance *before* they are able to make informed, adult decisions.
- 38. The chemistry and pharmacology of nicotine alone qualifies it as a potent and powerfully addictive drug, which is five to ten times more potent than cocaine or morphine in producing behavioural and psychic effects associated with addiction potential in humans, including measures of pleasure and liking.²² Nicotine fulfils all the criteria required for a drug of dependence.²³
- 39. Young people can rapidly develop nicotine dependence. With respect to nicotine from smoking conventional tobacco, symptoms can develop soon after a young person's first puff on a cigarette. Novice smokers often do not recognize the symptoms they experience as related to nicotine dependence.²⁴ A four-year cohort study of 1,246 students in the United States found that the most susceptible youths lose autonomy over tobacco within a day or two of first inhaling from a cigarette.²⁵ While it is clear that e-cigarettes deliver nicotine to users, we are not aware of any research into how addictive e-cigarettes might be to users that are children.
- 40. The brain continues to develop during adolescence, and exposure to exogenous substances such as nicotine can exert long-lasting adaptations during this vulnerable period, and research by Counotte et al. concluded:

..the brain and specifically the prefrontal cortex continue to develop during adolescence, making the adolescent brain uniquely different from the adult brain. One of the differences is that adolescents are more sensitive to the rewarding effects of nicotine, which may be a reason that many people start to smoke during adolescence. Both prospective and longitudinal human studies suggest that adolescent exposure to nicotine has long-term effects, among which are 1) the risk to develop substance use disorder and 2) various mental health problems, the most prevalent ones relating to affective disorders such as anxiety and depression. In addition, inasmuch our animal studies can be extrapolated to humans, adolescent exposure to nicotine may lead to decreased attention performance and increased impulsivity on the long-term. The latter observation in turn might promote the maintenance of smoking behaviour. Based on studies in human subjects, it is difficult to determine whether adolescent smoking underlies these problems, or whether smoking and mental health disorders have a common origin that predisposes an enhanced risk to the development thereof. In order to understand the effects of drugs of abuse on motivational systems, it is important to gain a better understanding of their development in the adolescent brain.²⁶

Royal College of Physicians (2007). Harm Reduction in Nicotine Addiction: Helping people who can't quit. RCP, London.

Gervais, A., et al. (2006). "Milestones in the natural course of onset of cigarette use among adolescents" in *Canadian Medical Association Journal*. 175(3), pp.255–261.

Di Franza, et al. (2007). "Symptoms of tobacco dependence after brief intermittent use: The development and assessment of nicotine dependence in Youth-2 study" in *Archives of Pediatrics and Adolescent Medicine*. 161(7), pp.704-710.

Counotte, D. et al. (2011). "Development of the motivational system during adolescence, and its sensitivity to disruption by nicotine" in *Developmental Cognitive Neuroscience;* 2011; 1 (2011), pp.430-443.

European Commission (2014). *E-cigarettes Myth Buster*. Available at: http://ec.europa.eu/health/tobacco/docs/tobacco_mythbuster_en.pdf

Gourlay, S. and McNeil, J. (1990). "Antismoking products" in *Medical Journal of Australia*. 153, pp.699-707.

The impact of nicotine on the developing adolescent brain, as delivered by e-cigarettes, is also described by Dutra et al.:

Although e-cigarettes deliver many fewer toxins and at much lower levels than conventional cigarettes, they contain nicotine, a highly addictive substance, in doses designed to mimic cigarettes. Animal models suggest that, through its effect on cholinergic pathways, nicotine may have permanent effects on the brain and behaviour such as dysregulation of the limbic system, which can lead to long-term difficulties with behavioural regulation, attention, memory, and motivation, among other functions. The adolescent human brain may be particularly vulnerable to the effects of nicotine because it is still developing.²⁰

Uncertainty about whether e-cigarettes are safe for children to use

- 41. We do not know about the effect of e-cigarette emissions on the developing lungs of young people. We are not aware of any long-term studies that suggest the use of e-cigarettes is safe, particularly for young people. The FPH says that nicotine, whether inhaled, ingested or in direct contact with the skin, can be particularly hazardous to the health and safety of certain populations such as children, young people, pregnant women, breastfeeding mothers, people with heart conditions and older people.¹⁰
- 42. The PHE-commissioned report on e-cigarettes says that evidence on the content and emission of electronic cigarettes is limited. Different electronic cigarette products are highly variable in the amount of nicotine they deliver in vapour and that the nicotine content indicated on a cartridge is not a reliable guide to likely nicotine delivery. The report also described how the risks between smoked tobacco cigarettes and e-cigarettes differ:

Cigarettes deliver nicotine in conjunction with a wide range of carcinogens and other toxins contained in tar, including nitrosamines, acetone, acetylene, DDT, lead, radioactive polonium, hydrogen cyanide, methanol, arsenic and cadmium, and vapour phase toxins such as carbon monoxide. In contrast, electronic cigarettes do not burn tobacco, so any toxins in vapour arise either from constituents and contaminants of the nicotine solution, and products of heating to generate vapour. The principal component other than nicotine is usually propylene glycol, which is not known to have adverse effects on the lung but has not to our knowledge been tested in models that approximate the repeated inhalation, sustained over many years, that electronic cigarettes involve. We are aware of two cases of lipoid pneumonia attributed to inhalation of electronic cigarette vapour, one in the peer-review literature the other a news report.

Despite some manufacturers' claims that electronic cigarettes are harmless there is also evidence that electronic cigarettes contain toxic substances, including small amounts of formaldehyde and acetaldehyde, which are carcinogenic to humans, and that in some cases vapour contains traces of carcinogenic nitrosamines, and some toxic metals such as cadmium, nickel and lead. Although levels of these substances are much lower than those in conventional cigarettes, regular exposure over many years is likely to present some degree of health hazard, though the magnitude of this effect is difficult to estimate.¹

- 43. Research indicates that young people may not be aware that e-cigarettes contain nicotine and can, therefore, be addictive. There is likely to be a general lack of understanding among young people about the safety of using e-cigarettes. Research undertaken in Cheshire and Merseyside found that young people aged 13-17 in that area 'showed a real uncertainty and lack of awareness of the potential risks and harms associated with e-cigarettes, current and proposed future regulation in the UK, and the actual chemical content and functional components of these devices'.⁶
- 44. Nicotine is classified as a poison and e-cigarette fluids for refilling certain types of e-cigarettes are toxic. In 2013, 139 calls were made to the National Poisons Information Service (NPIS) by health professionals seeking expert advice on how to treat members of the public suspected of nicotine poisoning. This is a sharp increase from the 29 reported cases in 2012 and 36 cases in the five years before that. The Director of the NPIS was reported as saying:

E-cigarette usage has increased significantly in recent years. The liquid found in e-cigarettes can be very harmful and I would urge anyone who uses e-cigarettes to make sure that the liquids are stored safely, and in particular away from children.²⁷

45. The European Commission says:

Nicotine is an addictive and toxic substance. The Commission has received notifications concerning the safety of e-cigarettes, i.e. there are significant differences between what is on the label and the true levels of nicotine inside. The long term effects of e-cigarettes on public health are not yet known.²³

Age of sale restrictions will support the position of the e-cigarette industry and retailers

- 46. Responsible manufacturers recommend that their products are for use by adults only. Responsible retailers already voluntarily restrict children from accessing e-cigarettes. However, there are some that do not. Research by the Trading Standards Institute, conducted across England in March 2014, showed that young people are most easily able to get e-cigarettes from market stalls and car boot sales, independent pharmacists and specialist e-cigarette suppliers. Sales of e-cigarettes were least frequently made from national newsagents and large retailers, which are stores that are already familiar with applying age of sale restrictions, including the sale of tobacco.²⁸
- 47. This proposal responds to calls from a number of manufacturers and retailers of e-cigarettes for a minimum age of sale. Age of sale restrictions that are consistent with the sale of tobacco and other age restricted products will support retailers in the operation of their business. The Electronic Cigarette Industry Trade Association has told the Department of Health that they support the introduction of age of sale controls for e-cigarettes.
- 48. There remains a need for clarity for how e-cigarettes should be sold, and many retailers are confused as to whether a minimum age of sale for e-cigarettes already exists. A recent study by the Trading Standards Institute of "test purchasing" of e-cigarettes by children showed that children were able to buy e-cigarettes in four out of every ten attempts. There were similar findings in July 2014 when an ITV investigation also found that a 17 year old was able to purchase e-cigarettes from a range of different types of shop, including pharmacies and supermarkets, with a third of outlets testing making a sale. In response to the investigation, the Sainsbury's, Waitrose and Co-Op supermarket chains each confirmed that they have policies to not sell e-cigarettes to children.²⁹

Supporting adolescents who want to quit smoking

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- 49. Adolescents who are currently smoking tobacco and wish to quit are likely to require support that combines a range of approaches. There is evidence to conclude that stop smoking medicines such as nicotine replacement therapies (NRT) used without behavioural support are not as effective in supporting adolescents to stop smoking as structured cessation services.
- 50. A Cochrane Review of evidence regarding tobacco cessation interventions for young people was published in 2010, which set out:

We identified 24 good quality studies (>5000 participants) that researched ways of helping teenagers to quit. Programmes that combine a variety of approaches, including taking into account the young person's preparation for quitting, support behavioural change and enhance motivation show promise. The number of trials and participants are beginning to be adequate to

Meikle, J. (2014). "E-cigarette poisoning figures soar as vaping habit spreads across UK" in The Guardian; 14 April 2014.

MacGregor, J. (2014). Youth access to e-cigarettes and associated products: A report commissioned by Public Health England. Available at: http://www.tradingstandards.gov.uk/templates/asset-relay.cfm?frmAssetFileID=75751

ITV (2014). "Third of outlets ITV News tested sold e-cigarette to 17-year-old" on *ITV News*, 16 July 2017. Available at: http://www.itv.com/news/2014-07-16/third-of-outlets-itv-news-tested-sold-e-cigarette-to-17-year-old/

provide evidence to judge effectiveness. Medications such as nicotine replacement and bupropion have not yet been shown to be successful with adolescents.³⁰

- 51. There is not sufficient evidence to conclude that e-cigarettes can assist children who want to stop smoking to quit. Children who want to quit smoking with the support of stop smoking medicines can continue to access existing forms of NRT, such as gums or patches. These NRT products are licensed for stop smoking by people down to the age of 12 years, and as they have been in use for a longer period than e-cigarettes, more is known about their safety profile.
- 52. Research suggests that children are not using e-cigarettes to quit smoking. The children that use e-cigarettes are most likely to be smokers, and that e-cigarette use is 'consistent with experimental behaviour or "poly-nicotine" use among current smokers'. 31
- 53. In the future, e-cigarettes that are licensed as a stop smoking medicine could be made available to children under the age of 18 years on prescription, but as a prescription only medicine.

Age of sale of e-cigarettes in other countries

- 54. The sale of e-cigarettes to minors has been banned in more than half of US states and there are proposals to set a federal minimum age of 18 years to use e-cigarettes in the US.³² Within the EU, Croatia, Slovakia, Spain, Italy and Latvia have set age of sale requirement for e-cigarettes.
- 55. The WHO recommends that retailers should be prohibited from selling electronic nicotine delivery system products such as e-cigarettes to minors.³³

Grimshaw G. and Stanton A. (2010). *Tobacco cessation interventions for young people (Review)*. Cochrane Collection. Available at: http://www.thecochranelibrary.com/userfiles/ccoch/file/World%20No%20Tobacco%20Day/CD003289.pdf

Lippert, A. (2014). "Do adolescent smokers use e-cigarettes to quit?" in *American Journal of Health Promotion*. In print (online first edition, accepted for publication on 15 March 2014).

Gostin, L and Glasner, A. (2014). "E-cigarettes, vaping and youth" in *JAMA*; 30 June 2014.

WHO (2014). Electronic Nicotine Delivery Systems: Report by WHO. Available at: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf

OPTIONS TO CONSIDER DURING CONSULTATION

56. Possible policy options to achieve the objective of preventing people under the age of 18 years from accessing nicotine inhaling products, such as electronic cigarettes, are set out below.

Option 1: Do Nothing

- 57. The Do Nothing Option is the baseline against which other options are assessed.
- 58. Details of the situation as it stands (and would remain under Option 1) are detailed in the 'description of the problem' as set out above.
- Option 2: Introduce a minimum age of sale of 18 years for nicotine inhaling products and introduce an offence of proxy purchasing nicotine inhaling products by adults for children (PREFERRED OPTION)
- 59. The preferred option is detailed in the section above. Costs and benefits are set out in the section below.

Option 3: Introducing a voluntary agreement with retailers that they will not sell to under 18's

- 60. This option involves introducing a voluntary agreement by retailers that they will not sell e-cigarettes to under 18's. The benefit of this option is that it is a non-regulatory proposal and therefore does not impose a direct cost to business.
- 61. The weakness of this option is that those retailers that sign up to the voluntary agreement are likely to be those retailers that currently refuse to sell to children under 18, therefore access to e-cigarettes will remain largely unchanged. The benefits of this proposal in terms of restricting access to nicotine inhaling products and a possible gateway into smoking will therefore be limited. It is likely to lead to inconsistent practice and confusion amongst retailers who would prefer the clarity that a statutory minimum age of sale would provide. Retailer organisations and the Electronic Cigarette Industry Trade Association (ECITA) both support age of sale legislation and the consistency it provides with other age restricted products, notably tobacco.
- 62. Whilst voluntary approaches may work in other areas of public health, the same principles cannot be applied to tobacco control where legislation has been shown to be the most effective way of achieving stringent age of sale controls and reducing the availability of tobacco to children and young people.
- 63. A voluntary agreement with retailers would not only result in inconsistency but may also be exploited by children and young people wishing to buy e-cigarette products. Thus it would not deliver the policy aim. Responsible retailers require the support of the law to effectively enforce age of sale restrictions and are supportive of a statutory minimum age of sale.
- 64. Research by the Trading Standards Institute, conducted across England in March 2014, showed that there is already confusion amongst retailers regarding the age at which e-cigarettes can be sold and this is despite the presence of age warnings on the majority (80%) of products purchased by volunteers during the study. ³⁰
- 65. Introducing a voluntary agreement not to sell to under 18's may put the volunteer retailers at a competitive disadvantage as they are losing out on a potential market that other retailers might be exploiting.
- 66. A voluntary agreement with retailers is not considered to be the most appropriate option to deliver a policy of reducing access of e-cigarettes to children.

67. Option 2 - Introducing (a) a statutory minimum age of sale of 18 years for nicotine inhaling products together with (b) an offence of proxy purchasing nicotine inhaling products by adults on behalf of children, is the preferred option.

Detailed quantification of the preferred option

Costs

68. Any restriction on age of sale may have impacts on the nicotine inhaling product supply chain, including manufacturers, importers, distributers and retailers. The proposed regulations would apply to any device that can be used for inhaling nicotine, as well as to refill cartridges and nicotine liquids for those devices.

Retailers

- 69. For retailers, it is likely that the impact of these regulations would be limited, given that many retailers are already voluntarily applying an age of sale restriction to the e-cigarettes they sell. This means that the impact would be focused on retailers who are currently purposely selling nicotine inhaling products to children. Research by the Trading Standards Institute, conducted across England in March 2014, showed that young people are most easily able to buy e-cigarettes from market stalls and car boot sales, independent pharmacists and specialist e-cigarette suppliers. Sales of e-cigarettes were least frequently made from national newsagents and large retailers, which are stores that are already familiar with applying age of sale restrictions, including the sale of tobacco.
- 70. In terms of the number of retail outlets potentially affected, the "Grocery Retail Structure 2013" records a total of 50,313 convenience stores/independent newsagents and petrol forecourts, plus 9,379 supermarkets in the UK, all of which could potentially sell e-cigarettes. Research undertaken in June-July 2013 into the retail availability and in-store marketing of e-cigarettes in London found high availability of e-cigarettes in small and large stores, with an overall availability of 57% in the study sample. A number of national supermarket chains however have confirmed that they have policies to not sell e-cigarettes to people under the age of 18 years. It is not known how many market stalls sell e-cigarettes.
- 71. E-cigarettes are also starting to be sold in pharmacies. Alliance Boots (which comprises both community pharmacies and large health and beauty stores) started selling Fontem's "Puritane" branded e-cigarettes in February 2014 and Lloyd's Pharmacy stocks Nicoventure's "Vype" branded e-cigarettes in its 1600 UK stores. There are 11,500 community pharmacies in England and 700 in Wales, plus health and beauty stores, however we have no evidence regarding how many sell (or intend in the future to sell) e-cigarettes.
- 72. It is difficult to quantify the total cost to retailers as we do not have comprehensive data on the number of retailers currently selling e-cigarettes and related products. Our assessment below is, therefore, based on removing all current users of e-cigarettes aged under-18 years from the e-cigarette market.
- 73. Given that a number of supermarkets have confirmed that they already prohibit sale to under 18's, we estimate that most of the impact of this policy will be as a result of independent retailers and stall owners refraining from selling to under 18's. Primarily targeting independent retailers as opposed to national chains will likely increase enforcement and compliance costs, as enforcement will be at the unit level as opposed to national/ Head Office level.
- 74. Local authority trading standards officers would be responsible for enforcing legislation relating to the age of sale for nicotine inhaling products covered by these proposed regulations. The proposal

The Pharmaceutical Journal. (Feb 2014). Boots and Lloyds Pharmacy join the vaping fold by selling e-cigarettes. Available at: http://www.pjonline.com/news/boots and lloyds join the vaping fold by selling ecigarettes

The Grocer (2013). Grocery Retail Structure. Available at: http://www.thegrocer.co.uk/reports-and-advice/rankings/grocery-retail-structure-2013/343572.article

- would bring e-cigarettes into the age restricted product category, which includes a range of products such as tobacco, alcohol, butane gas lighter refills and fireworks.
- 75. Government would encourage local authorities to continue to take a "compliance building" approach with retailers, so that retailers are aware that nicotine inhaling products are no longer available for purchase by children. We would encourage enforcement action to be taken especially in cases where legislation has been persistently breached.
- 76. The Department of Health would work with retailer bodies, the retail trade press and the e-cigarette industry to build understanding of new rules as widely as possible. We do not anticipate that setting an age of sale for nicotine inhaling products will bring any significant new burdens on retail transactions, as retailers are already used to checking age before selling a wide range of goods.

Assessing direct costs to business

- 77. Given the newness of this market, data is not as widely available compared to, say, tobacco. Therefore two assessments are made as to the impact of removing under-18 year olds from the ecigarette market:
 - A bottom up approach based on estimating annual use of e-cigarettes by under 18s and the associated financial costs; and
 - a top down approach based on apportioning the size of the e-cigarette market to under 18s

Bottom-up approach

- 78. By applying national population profiles to the results of an extensive survey of 2,178 young people aged 11-17 years, undertaken across Great Britain by YouGov for ASH in March 2013³⁶, we estimate that there are 12,766^{37,38} regular users of e-cigarettes under 18 years of age in England and Wales. Approximately 16-32% (2,046 4,092) of these children having never smoked tobacco cigarettes before taking up e-cigarettes.
- 79. NB: It must be noted that the estimated proportion of regular users that were formerly non-smokers as stated above is based on one or two non-smokers of the 2,178 children questioned who claimed to use e-cigarettes more than once a week.
- 80. It must also be noted that the estimated number of regular users under the age of 18 in the UK is based on 6 children out of the 2,178 questioned, who claimed to use e-cigarettes more than once a week. We acknowledge that the relatively small number of respondents limits the preciseness of our estimates.
- 81. The ASH survey found that that of the 2,178 respondents, 103 (4.7%) had "tried e-cigarettes once or twice" and 6 (0.287%) currently used e-cigarettes more than once a week. Applying these rates to the England and Wales 11-17 year old projected population estimates for 2015 would equate to:
 - 12,766 regular e-cigarette users, and
 - 209,873 e-cigarette "experimenters" (i.e., children using the products on only a handful of occasions)
- 82. We believe that it is plausible that e-cigarette use among young people may increase in line with international experience³⁹ and that uptake by non-smokers may also continue to rise.

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Action on Smoking and Health (2014). ASH briefing: Use of electronic cigarettes in Great Britain. Available at: www.ash.org.uk/files/documents/ASH_891.pdf

^{0.287%} of 4,455,897 11-17 year olds in England and Wales, based 2015 ONS England & Wales population projection

ONS. Population Projection Estimates for England and Wales, 2015

See, for example, para 35

- 83. One disposable e-cigarette is priced between £1 £8⁴⁰, and is thought to be the equivalent of approximately 30-40 tobacco cigarettes. Purchasing a refillable e-cigarette package (with a charger and nicotine cartridges) priced between £30 £50, with refill cartridges £2 £17 and being the equivalent of approximately 30 tobacco cigarettes in terms of number of puffs, makes e-cigarettes approximately three times cheaper than tobacco cigarettes⁴¹. We have assumed that younger users will be more likely to purchase disposable e-cigarettes as they are cheaper, more readily available and more convenient for them to use.
- 84. Using data on e-cigarette consumption among adults taken from the University College London Smoking Toolkit Study⁴², we calculated adult consumption of e-cigarettes relative to tobacco cigarettes; we then applied this proportion to tobacco consumption by 11-17 year olds to produce an estimated average consumption among under-18 regular e-cigarette users of 23 e-cigarettes per year.
- 85. This means total regular users consume around 296,000 e-cigarettes per year. If we assume that each experimental user consumes the e-cigarette equivalent of one tobacco cigarette, the total number of e-cigarettes purchased would be around 303,000. We think this is a reasonable central estimate of usage. At one extreme, everyone who tries an e-cigarette may buy an e-cigarette. We do however feel this is probably too high an estimate as children are likely to club together to purchase and share, or they may try a drag or two from a friend or relative who uses an e-cigarette. At the other end of the spectrum we could assume that all experimenters are simply users of devices from friends. In this case we may expect the impact on sales to be very small but again we think this is unlikely.
- 86. Assuming a price estimate of £4 per disposable e-cigarette and a 40%⁴³ profit margin, eliminating all under-18s from the current e-cigarette market in England and Wales would lead to a loss of profit of around £480,000 per year. This is our central estimate of the direct impact of the legislation on retailers in year one.
- 87. There are, however, uncertainties with this figure:
 - The profit margin used in this assumption is likely to change as the market evolves. Given the dynamic and evolving nature of the e-cigarette market, we expect profit margins to decrease as competition increases. Using a more moderate 20% profit margin would halve the cost to business to around £240k.
 - A 40% profit margin is a gross figure and does not represent the profitability of goods which
 would replace this lost market (e.g., if an alternative product was purchased by the young person
 instead of the e-cigarette with a 10% profit margin, the impact would reduce to around £360k –
 this £120k reduction would be classed as an indirect effect). We do not know what young people
 might purchase in place of e-cigarettes (likely to be a multitude of different things with different
 profit margins for different shops), so cannot put an accurate figure into the model.

4) Amazon.co.uk

5) http://www.vapestick.co.uk/v1-disposable-electronic-cigarettes-special-offer.html

¹⁾ http://www.electrictobacconist.co.uk/disposable-e-cigarettes-c4#t29

^{2) &}lt;a href="http://nicolites-shop.co.uk/index.php?route=product/category&path=77">http://nicolites-shop.co.uk/index.php?route=product/category&path=77

^{3) &}lt;a href="http://www.10motives.com/disposables/">http://www.10motives.com/disposables/

⁴⁾ Amazon.co.uk

Assume disposable e-cigarette priced at £4 and delivers 300 puffs. Average RRP for a pack of 20 cigarettes (estimated 200 puffs) was £7.98 in 2013. (£7.98 x 1.5 = £11.97). Average RRP according to The Tobacco Manufacturers Association. Available at: http://www.the-tma.org.uk/tma-publications-research/facts-figures/uk-cigarette-prices/

West R, et al. (2014). Trends in electronic cigarette use in England, Smoking Toolkit Study. Available at: http://www.smokinginengland.info/latest-statistics/

High margin options and growing fast, Scottish Grocer, March 2013. Available at: http://www.scottishgrocer.co.uk/2013/03/high-margin-options-and-growing-fast/

Under 18s are likely to be using cheaper disposable e-cigarettes. If a disposable e-cigarette
priced at £1 rather than £4 is used in this modelling, the impact would reduce to around £120k.⁴⁴

88. Exploring a high cost scenario:

- If all experimenters actually purchase one e-cigarette, rather than sharing with friends, the total number of e-cigarettes consumed by under 18s would be around 506,000 per year, and the cost to retailers of eliminating them from the market would be £809k per year in lost profits.
- 89. Considering this data, the total direct impact to retailers could plausibly be in the range £120k to £809k in year 1 with our central estimate at £480k.

Top-down approach

- 90. In order to try to validate our assessment of the total cost to retailers we also use a slightly different way to estimate the size of the under 18 market using a top down approach.
- 91. The "bricks and mortar" retail market for e-cigarettes in the UK was said to be worth £91.3m⁴⁵ in January 2014. The size of the total market including online sales is likely to be more than twice this figure, as according to the Electronic Cigarette Industry Trade Association (ECITA), 'online sales are slightly over retail sales'⁴⁶. An estimate of the size of the total UK market is, therefore, £187.2m.

We encourage anyone with further relevant information on the total size of the e-cigarette market to make it available through the consultation.

- 92. ASH estimates that there are 2.1 million e-cigarette users in the UK. Assuming that 12,766⁴⁷ of these are regular users aged 11-17 (as calculated in the "Bottom Up Approach" section), this implies that regular users under the age of 18 comprise around 0.61% of the market, worth around £1.14m. Using a top down approach and assuming a 40% profit margin leads to a **maximum loss of profit of around £455,000 per year from regular users.** From para 87, our bottom up approach would suggest lost profit from regular users of around £480k (296,000 e-cigarettes, priced at £4 each with a 40% profit margin).
- 93. The top down approach therefore lies within our range of estimates from the bottom up approach and is very similar in magnitude to our central estimate. All of these impacts assume 100% compliance with the new age limit.
- 94. Furthermore, the Government will propose that any nicotine inhaling products that are licensed as medicines would not be covered by these age of sale provisions, as the products are already regulated under relevant medicines legislation. That means that under-18s trying to quit smoking would continue to be able to access nicotine inhaling products that are licensed but only under medical supervision e.g. by way of prescription. Other forms of nicotine replacement therapy, such as gums and patches, would continue to be available to anyone from the age of 12 upwards who are trying to quit smoking. This would also be relevant to profits for shops where such products can be sourced.

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Daily Mail Online. (July 2013). 'The bargain basement e-cigarette: Worlds cheapest nicotine vaporiser goes on sale in the UK – and it costs just £1'. Available at:

http://www.dailymail.co.uk/health/article-2380669/Rise-e-cigarette-Worlds-cheapest-nicotine-vaporiser-goes-sale-UK--costs-just-1.html

Chittock, M. (2014). Focus on e-cigarettes: A touch of the vapours. *The Grocer*, February 15th: 51-52,54 http://www.thegrocer.co.uk/reports-and-advice/rankings/grocery-retail-structure-2013/343572.article

PJ Online. (2014). Quote from Katherine Devlin, President of ECITA. Available at: http://www.ecigclick.co.uk/boots-and-lloyds-pharmacy-to-sell-e-cigarettes-made-by-tobacco-companies/

⁴⁷ Refer to earlier calculations.

Market Growth

- 95. The market for e-cigarettes is fast moving. The analysis above is based on applying a 2013 survey to 2015 population projections. We know however that there are likely to be three main effects (along with population growth) in determining the number of under 18s users in the future:
 - The substitution between tobacco products and e-cigarettes for current tobacco smokers
 - The number of new smokers (since most e-cigarette users are tobacco users)
 - The number of new regular users who have never smoked tobacco.
- 96. We know that the uptake of e-cigarettes amongst the adult population has grown in the last 3 years, although the growth rate is slowing down⁴⁸. We also know that the prevalence of tobacco use amongst 16 and 17 year olds has more than halved in the last 10 years 49. Assuming e-cigarette growth continues at 10% per year, alongside the under 18 tobacco prevalence continuing to fall and applying it to the England and Wales population projection for 11 to 17 year olds over the next 10 years indicates an increasing amount of estimated e-cigarette use - from around 303k e-cigarettes in 2015 to around 545k in 2024. This excludes any downwards impact we expect the Tobacco Products Directive to have when it is implemented in 2016.

<u>- Numb</u>	Number of e-cigarettes consumed by under 18s, 2015 to 2024.						
			Assumed				
			uptake				
			of e-cigs	Regular			
		Assumed	for	use			
		under 18	current	amongst		Total	
		tobacco	smokers	non-		under	Total e-
	Under 18	cigarette	(dual	cigarette		18 e-cig	cigs per
Year	рор	prevalence	use)	users	Experimenters	users	year
		-			-		
2015	4,455,897	9.7%	8,674	4,092	209,873	222,639	302,772
2016	4,443,678	9.0%	8,819	4,489	230,227	243,535	315,992
2017	4,467,807	8.3%	9,039	4,964	254,625	268,628	332,932
2010						•••	
2018	4,525,594	7.7%	9,334	5,531	283,710	298,576	353,875
2010	4 624 005	7.40/	0.740	C 24.4	240 720	224 664	270 762
2019	4,621,985	7.1%	9,719	6,214	318,728	334,661	379,763
2020	4,727,025	6.6%	10,133	6,991	358,569	375,692	408,685
2020	4,727,023	0.076	10,133	0,331	338,309	373,032	400,003
2021	4,830,344	6.1%	10,556	7,858	403,046	421,460	440,056
2021	+,030,344	0.170	10,550	7,030	+03,040	721,700	440,030
2022	4,926,044	5.7%	10,974	8,815	452,135	471,924	473,564
	,,	- ,-	- ,-	,	,	,-	-,
2023	5,021,416	5.3%	11,405	9,884	506,977	528,266	510,129
2024	5,071,196	4.9%	11,742	10,980	563,204	585,926	545,212

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ONS General Household Survey 2001-2007, ONS General Lifestyle Survey 2008-2011. Projections based on current trend.

ONS General Household Survey 2001-2007, ONS General Lifestyle Survey 2008-2011.

Manufacturers and distributers (excluding retailers)

- 97. We have limited data on the costs and profits of *manufacturers* and *distributers*, and wish to gain more relevant information through the consultation process. However given the similarities between the tobacco market and the e-cigarette market and in recognition that the majority of e-cigarette sales are brands now owned by tobacco companies, we have used information from the tobacco industry to inform estimates of profitability and ownership.
- 98. In attributing a share of impact to the UK, for OITO and EANCB purposes a "GDP approach" is adopted to assess the direct impact on UK-based activities. We estimate that only around 10% of ecigarette manufacturing is physically located within the borders of the UK. Information to confirm this assessment is sought during consultation. The impact on UK manufacture businesses, therefore, of setting a minimum age of sale can therefore be calculated as follows:
- 99. If we take a 35% profit margin⁵⁰ (average operating profit of tobacco manufacturers calculated from information contained in the 2013 annual reports of BAT and JTI) and reckon 10% of manufacturers' profits from UK consumption is UK-based, then the total UK lost profit from eliminating users under 18 from the market would be around £25,000 in year one for OITO and EANCB purposes (and would be £250,000 if 100% of activity was UK-based). This is calculated by taking our estimate of the total number of e-cigarettes consumed by under 18s in 2015 from Table 1, estimating an average £2.40 wholesale price (which is the average £4 retail price less the 40% retailer profit margin) and applying a 35% profit margin and a 10% UK-based share of activity.
- 100. For NPV purposes, however, the ultimate impacts on UK shareholders from foreign-based activity, as well as UK-based activity of e-cigarette manufacturers is pertinent. Therefore, for the UK Net Present Value we consider this impact by a separate estimate that also happens to be 10%, of the share of the ownership of e-cigarettes sold in the UK that is UK resident. Considering the vast majority of e-cigarette brands are now owned by tobacco companies, the 10% is taken from tobacco Impact Assessments, such as the ones for standardised packaging⁵¹.
- 101. We have no information on the market for distributers, but expect that it will be a low profit margin industry given its competitiveness and low barriers to entry. Therefore we expect any lost profits to be small, but welcome views during consultation.
- 102. Many responsible e-cigarette manufacturers already label their products and make clear on promotional material and on their websites that e-cigarettes should not be sold to people under the age of 18 years.

We encourage anyone with further relevant information on how an age of sale for e-cigarettes would impact on manufacturers and distributors to make it available through the consultation, especially our assumption that around only 10% of e-cigarette production is UK-based.

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Average of JTI international markets and BAT Western Europe profit margins from 2013 Annual Reports

www.gov.uk/government/consultations/standardised-packaging -of-tobacco-products-draft-regulations

There is uncertainty in this 10% assumption which is not based on any one specific source. However, it does draw on three pieces of information. Firstly, 10% is a figure used for previous IAs for the proportion of multinational profits that should be considered in the NPV (see Statutory scheme for pricing branded medicines Impact Assessment available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/207886/impact_assessment_statutory_scheme_brande_d_med.pdf). Secondly there is some information on the shareholdings of multinational tobacco companies; however, this is information about the institutional shareholdings rather than the individual shareholdings. Thirdly, if one was to assume a perfectly globalised market where all companies were multinational, then the proportion of profits received by UK shareholders would be approximately the ratio of GDP for the UK to that of the world which is around 3-4% (IMF - World Economic Outlook Database available at http://www.imf.org/external/pubs/ft/weo/2012/02/weodata/index.aspx using 2014 figures, current prices i.e.no purchasing power parity adjustment which would decrease the value to 2-3%).

Staff Training/Awareness

103. It is anticipated that there will be a small one-off cost for retailers in terms of training staff and raising awareness of the new age of sale restriction and the products to which it applies. There will be a very low ongoing cost in terms of staff churn. Retailers are already familiar with the concept of age of sale across a range of products (i.e. alcohol, knives, fireworks, tobacco) and the addition of a new product to existing training should not be unduly burdensome. These costs have not been quantified but we assume they are not significant and immaterial compared to the impacts modelled.

However we would welcome views, especially from the retail sector, during consultation on this assumption.

Consumers

- 104. The main consumer group affected are the children who are no longer able to purchase (or purchase via an adult) a nicotine inhaling product who are currently doing so.
- 105. We expect that children will purchase other goods and services with the money they would previously spend on e-cigarettes. If e-cigarettes were a non-addictive product, we would assume, therefore, that children were losing some consumer surplus from this change in availability. The addictive nature of nicotine makes it difficult to make such an assumption. The addictiveness of nicotine may induce children to make sub-optimal consumption decisions. We therefore note that there may be a potential effect on consumer surplus, but we do not attempt to calculate it.

We welcome views on this approach.

Enforcement

106. There may be a cost to local authorities as trading standards officers will be required to monitor and enforce the regulations. As the regulations for e-cigarettes are similar to existing age of sale provisions surrounding alcohol and tobacco, that are currently enforced by trading standards officers, we anticipate that the additional cost of monitoring e-cigarette sale and purchase will be marginal; we therefore have not attempted to quantify this cost.

We encourage anyone with any views or evidence concerning enforcement costs, to make it available during consultation.

Second round impacts and indirect costs

- 107. The direct costs of loss of profits from eliminating under 18s from the e-cigarette market to retailers and manufacturers are likely to be partially offset by spending on goods and services elsewhere in the economy.
- 108. In the long run we would expect the profit margins and returns on capital to equalise throughout the economy, and the long run effects of switching spending between goods and services would lead to no loss of output for the economy as a whole.
- 109. E-cigarettes currently attract a high profit margin (of around 40% to retailers) owing to them being a relatively new and novel product and also being addictive. Initially, any spending on other goods and service would be likely to deliver lower profit margins, for illustration we assume a 10% profit margin from redirected spending. For comparison we assume that profit margins for e-cigarettes fall to 20% in 2016 and fall and remain at 10% from 2017 onwards as the market matures and competition eliminates this super normal profit (by way of reduced retail prices). We include these second round impacts of spending elsewhere in the NPV, but would welcome further evidence during consultation on the treatment and calculation of these effects.

110. A potential knock-on effect of prohibiting sales to under 18's is that by preventing people from starting to use e-cigarettes before the age of 18, it decreases the chances of them becoming users as adults. This is demonstrated with tobacco where we know that the addictions starts in childhood and adolescence - two-thirds of all smokers started before they were 18. This will reduce the numbers of young adult consumers, which will impact profits in the adult market. As they will legally be able to purchase e-cigarettes, however, we categorise this impact as an indirect cost; the policy influences behaviour in this case, but it is not a determinant. We assume that any reductions in profit on e-cigarettes in the future due to this effect are offset by increases in profits for other industries.

Total Impact

- 111. We believe the direct costs to retailers will be in terms of staff training and some loss of profits. The assessment of loss of profits above is based on removing all users under the age of 18 from the market. The impact on manufacturers is assumed to be small, but we welcome further comments on this estimate.
- 112. There are no additional direct costs imposed by the regulations in terms of retailers complying with the regulations. For example, there is no requirement to display signage on this specific age restriction (like there is for tobacco), although retailers may choose to do so voluntarily. We consider the total costs to business to be small.
- 113. Offsetting these costs, there will be increased profits to retailers selling goods other than ecigarettes. We assume for this consultation that the average profit margin for retailers is 10%. We classify this as indirect.

Table 3 – Total discounted cost impacts on e-cigarette supply chain over the next 10 years

	DIRECT			INDIRECT			
	e-cigarette	e-cigarette					
	profit	profit		Profit	Profit	Total	
	eliminated	eliminated	Total	increases	increases	increased	Net Impact to
	from	from	eliminated	elsewhere for	elsewhere for	profit	retailers and
Year	retailers	manufacturers	profit	retailers	manufacturers	elsewhere	manufacturers
2015	£468,053	£24,573	£492,626	£117,013.20	£7,021	£124,034	£368,592
2016	£176,989	£24,778	£201,768	£88,494.62	£7,080	£95,574	£106,194
2017	£80,076	£25,224	£105,300	£80,076	£7,207	£87,283	£18,017
2018	£82,235	£25,904	£108,139	£82,235	£7,401	£89,636	£18,503
2019	£85,267	£26,859	£112,126	£85,267	£7,674	£92,941	£19,185
2020	£88,657	£27,927	£116,585	£88,657	£7,979	£96,637	£19,948
2021	£92,235	£29,054	£121,289	£92,235	£8,301	£100,536	£20,753
2022	£95,901	£30,209	£126,110	£95,901	£8,631	£104,532	£21,578
2023	£99,813	£31,441	£131,254	£99,813	£8,983	£108,796	£22,458
2024	£103,070	£32,467	£135,536	£103,070	£9,276	£112,346	£23,191
PVC	£1,372,296	£278,436	£1,650,732	£932,762	£79,553	£1,012,315	£638,417

Assumptions:

- E-cigarette retailers' profit margins are 40% in year 1, 20% in year 2, 10% in year 3 onwards.
- E-cigarette manufacturers profit margin on wholesale price is 35%
- Retail price assumed to drop to £3 in year 2 and £2.67 in year3 onwards.
- Retailer & manufacturers general margin for other goods and services is assumed at 10%.
- All costs discounted at 3.5% per year

We encourage anyone with relevant information on the categorisation of direct and indirect impacts to
make it available during consultation.

Benefits

Informed Choice

- 114. It is assumed that under 18's are less able to make rational informed decisions that might affect the rest of their life.
- 115. Nicotine is an addictive substance, when addiction is factored into the decision making process, it can be argued that consumers are less able to exercise choice. The benefit of Option 2 is in aiding under 18's to make more informed choices and in potentially preventing addiction.
- 116. As discussed in paragraph 105, due to nicotine being an addictive good, impact on consumer surplus varies from that of a normal good. Although an individual's initial consumption may be driven by the rational desire to consume the product (and will result in consumer surplus), following addiction to that product, the decision to consume is no longer driven by the desire to consume but rather the compulsion to satisfy the symptoms of nicotine addiction. As a result, individuals addicted nicotine, first as children and then as adults, are forced to spend money on alleviating symptoms of addiction that they might otherwise spend on other goods and services that would give them positive pleasure. We conclude therefore that the expenditure on other products in place of e-cigarettes by people addicted to nicotine should be counted as a benefit of the proposed age of sale restriction, as this spending will yield more pleasure. We have not attempted to calculate this effect at this stage as we lack information on the number of children that would become addicted to nicotine and the duration of their addiction, but would welcome views during consultation on this effect and how it might be quantified.

Preventing a gateway into tobacco smoking

117. For every regular user for whom e-cigarette use acts as a gateway into smoking, and as a result develops an addiction to smoking tobacco, we have estimated that, on average, they would lose 1 discounted life year⁵² through increased mortality risk (a weighted average of the life year gain depending on duration of addiction). Preventing a gateway into smoking tobacco results in an average 1 life year gain per individual. This life gain is valued at £60,000⁵³ per person, if this policy prevents a minimum of 12 people from taking up tobacco smoking over the 10 year period, the benefits will outweigh the costs.

We encourage anyone with further relevant information on under 18's use of e-cigarettes as a gateway in or out of smoking, and how an age of sale for e-cigarettes would impact on these users, to make it available through the consultation. We will use this information to make a central estimate for benefits of eliminating this gateway.

Preventing a gateway out of smoking

- 118. It is possible that this ban would make it more difficult for children who smoke tobacco who perceive using e-cigarettes as a way of quitting tobacco smoking.
- 119. Evidence is scarce on the effectiveness of using e-cigarettes to quit tobacco smoking and even scarcer for the effectiveness in children. We therefore note here that there is a possible dis-benefit and would welcome further evidence and views on this at consultation.

Overall

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See Annex A

DH assigns a value of £60,000 to a Quality Adjusted Life Year. Where Quality Adjusted Life Year estimates are not readily available, and it is appropriate this value is used for Life Years. This is consistent with similar valuation of policies that mitigate mortality or morbidity risk by other Government departments, based upon studies of what members of the public are on average willing to spend to reduce their own mortality risk, or to improve their own health outcomes.

120. Quantitative evidence around the impact of this proposal on individuals, businesses, the NHS and wider society is relatively weak, but has been presented where it exists. Evidence on the addictiveness of nicotine however is very strong; a key benefit of this policy is in avoiding addiction in childhood. The importance of this proposal lies primarily in its potential to prevent addiction as well as its potential to block a possible gateway into smoking; it therefore contributes towards the Governments overall objectives re smoking reduction.

Specific Impact Tests

Small and Micro Business Assessment (SaMBA)

- 121. As discussed in paragraphs 69 to 76, in terms of the number of retail outlets potentially affected, the "Grocery Retail Structure 2013" records a total of 50,313 convenience stores/independent newsagents and petrol forecourts, plus 9,379 supermarkets in the UK, all of which could potentially sell e-cigarettes. The convenience stores and petrol forecourts that do not belong to a national chain (i.e. unaffiliated independents) could be recognised as small and micro businesses.
- 122. A number of large supermarkets have confirmed to us that they already have a voluntary practice in place not to sell e-cigarettes to under 18s. It is likely therefore that the under 18s who are currently purchasing e-cigarette products, are more likely to be doing so from small and micro business retailers and therefore we expect the loss of profits associated with fewer sales to impact on small and micro business.
- 123. Given that many of these businesses have not chosen a voluntary approach of restricting sales (as per the large supermarkets) legislation is needed to restrict sales to under 18s and to ensure consistency and clarity for retailers. As stated in paragraphs 62 and 63, whilst voluntary approaches may work in other areas of public health, the same principles cannot be applied to tobacco control where legislation has been shown to be the most effective way of achieving stringent age of sale controls. A voluntary agreement with retailers would not only result in inconsistency but is likely to be exploited by children and young people wishing to buy e-cigarettes and associated products such as e-liquids containing nicotine. Thus it would not deliver the policy aims.

We seek views in the consultation as to how much of the identified lost profits are likely to affect small and micro businesses. We note that these direct costs in the form of lost profits will be matched to some extent by increased indirect benefits from increased profits in other industries, of which small and micro businesses are likely to benefit.

- 124. We do not believe exempting small and micro business from this regulation would enable any of the identified benefits to be realised, given that the benefits are contingent on reduced e-cigarette uptake. This would not happen if children could simply switch their purchase from one type of shop to another.
- 125. As stated in paragraph 75 the Government would encourage local authorities to continue to take a "compliance building" approach with retailers, so that retailers are fully aware that nicotine inhaling products are no longer available for purchase by children and young people. (We would encourage, however, enforcement action to be taken especially in cases where legislation has been persistently breached.) Given that specialist e-cigarette shops and small and micro retailers may be more unfamiliar with age of sale restrictions, a compliance building approach should mean that offending small and micro retailers will not disproportionately suffer if they offend whilst becoming familiar with the new regulations.
- 126. We are assuming that since the vast majority of the independent e-cigarette manufacturers have been acquired by the tobacco industry firm over the last few years, that no or negligible manufacturer profits are made by small and micro businesses.

We encourage anyone with information and data to the contrary to make it known via consultation. Little is known about the distributer market, and we welcome views on their categorisation into small and micro businesses.

127. If anyone has more evidence on the costs and benefits to small and micro businesses that are not addressed in this impact assessment they are encouraged to make these known via the

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The Grocer (2013). Grocery Retail Structure. Available at: http://www.thegrocer.co.uk/reports-and-advice/rankings/grocery-retail-structure-2013/343572.article

consultation, or if they are any ways that the impact on small and micro businesses could be reduced whilst maintaining the public health benefits.

Competition Test

128. We do not anticipate any reduction or increases in the competitiveness of the e-cigarette industry by introducing a minimum age of sale of 18.

Equalities Test

129. We have conducted a separate analysis of the likely impact of this policy on all the relevant equality characteristics under the public sector equality duty. This Equalities Analysis will be published alongside this Impact Assessment as part of the public consultation.

130.

Sustainability Test

131. We do not anticipate any reduction or increases in the sustainability of the e-cigarette industry by introducing a minimum age of sale, given that sales to under 18s represent a very low proportion of total sales.

Environmental Test

132. We do not anticipate any impact on the environment.